

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Milanesi v. C.R. Bard,
Case No. 2:18-cv-01320

MOTIONS IN LIMINE OPINION & ORDER NO. 17

Plaintiffs' Motion *in Limine* ("MIL") No. 4

Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi filed a Motion *in Limine* to Preclude Any Evidence or Argument Concerning Defendants' Employees, Witnesses, Expert Witnesses, and/or Their Family Members or Friends' Personal Experience with Hernia Mesh (Plaintiffs' MIL No. 4, ECF No. 202), which was opposed by Defendants C.R. Bard, Inc. and Davol, Inc (ECF No. 238). For the reasons that follow, the Court **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' Motion.

I. Background¹

The Milanesis' case will be tried as the second bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict

¹ For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

Litigation described the cases in this MDL as “shar[ing] common factual questions arising out of allegations that defects in defendants’ polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections.” (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of the Ventralex Large Hernia Patch, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive damages.

The relevant facts here are that Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. Mr. Milanesi had the Ventralex Large Hernia Patch implanted ten years earlier to repair a hernia.

In the Plaintiffs’ MIL No. 4, they move to exclude under Federal Rule of Evidence 104(a) all evidence or argument regarding Defendants’ employees, witnesses, expert witnesses, and/or their family members’ personal experience with hernia mesh.

II. Standards

“Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*.” *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such

motions “has developed pursuant to the district court’s inherent authority to manage the course of trials.” *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). “The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial.” *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because “a court is almost always better situated during the actual trial to assess the value and utility of evidence.” *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); accord *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—“evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.” *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; see also *Koch*, 2 F. Supp. 2d at 1388 (“[A] court is almost always better situated during the actual trial to assess the value and utility of evidence.”). The denial, in whole or in part, of a motion *in limine* does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Evid. 401. “Irrelevant evidence is” inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 “if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court’s sound discretion.

Frye v. CSX Trans., Inc., 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) (“In reviewing the trial court’s decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.”).

III. Analysis

Both parties agree that a similar issue was before this Court in the first bellwether case, *Johns v. C. R. Bard, Inc., et al.*, Case No 2:18-cv-01509, where the *Johns* plaintiff moved to exclude all evidence related to Defendants’ employees, witnesses, expert witnesses, and/or their family members’ personal experience with mesh. The Court granted in part and denied in part the motion, concluding that Defendants could introduce limited evidence regarding the Vice President of Regulatory Affairs Stephanie Baker’s implantation with the hernia mesh device at issue in that case. (Case No 2:18-cv-01509, ECF No. 332 at PageID #17889.)

Plaintiffs here argue that the Court should exclude all evidence or argument regarding personal experience with and recommendations of Defendants’ hernia mesh products. Plaintiffs claim that such evidence is “wholly irrelevant and highly prejudicial,” and that it will create “unnecessary delay and confusion because it may be used to support the improper inference that a witness’ good experience with hernia mesh somehow equates to the safety of the Ventralex Hernia Patch or that the Defendants’ conduct must have been reasonable.” (Pls’ MIL No. 4, ECF No. 202 at PageID #14717.) Plaintiffs also argue that if the Court does determine that such evidence is admissible, Plaintiffs should be permitted additional discovery to learn the details of such personal experience and recommendations to be able to effectively cross-examine witnesses at trial. Defendants claim that Defendants’ corporate knowledge and intent are at issue in this case, and

“evidence that [Defendants’] executives personally used and/or recommended hernia mesh devices containing polypropylene and/or [expanded polytetrafluoroethylene (‘ePTFE’)] is directly relevant to rebut Plaintiffs’ claims.” (Defs’ Mem. in Opp., ECF No. 238 at PageID #15346.) This Court agrees. Plaintiffs’ claims allege intentional misconduct on the part of Defendants, and testimony that Defendants’ top executives personally used or recommended Defendants’ hernia mesh devices is relevant to rebut Plaintiffs’ arguments that Defendants knew their products were unsafe.

In *Johns*, the Court allowed limited testimony regarding personal experience with Defendants’ hernia mesh products. At the motions *in limine* hearing on September 10, 2021, the Court concluded:

[D]ecision makers who expose themselves to the same risks would be some evidence of the company’s intent, whether it knew something was dangerous . . . [Ms. Baker] obviously can be cross-examined, but she had the surgery, used the same device, and she was directly involved in the process to bring the product to market. So, to be clear, and I think everyone understands this, she is not a witness to testify that the product was safe and no inference is to be drawn that [if] it worked for her, it’s got to work for everybody. We know that’s not proper. But it does go to knowledge and notice of Bard.

(Case No 2:18-cv-01509, ECF No. 345 at PageID #18608.) The same reasoning applies here. A decision maker’s personal use or recommendation of Defendants’ polypropylene and/or ePTFE hernia mesh may be used to show the Defendants’ state of mind. This evidence may not, however, be used to show that the Defendants’ hernia mesh products are safe and effective.

Plaintiffs point specifically to the testimony of Dr. John DeFord and Roger Darois in the *Johns* trial. During the trial, Dr. DeFord and Mr. Darois testified that they had recommended Defendants’ hernia mesh products to friends and family. (Case No 2:18-cv-01509, ECF No. 567 at PageID #31748–49; Case No 2:18-cv-01509, ECF No. 577 at PageID #32035–36.) Plaintiffs claim that such recommendations “cannot possibly be perceived as anything but a testament to the safety and efficacy of [Defendants’] products.” (Pls’ MIL No. 4, ECF No. 202 at PageID #14716.)

Plaintiffs also argue that, should the Court allow Defendants' witnesses to testify that they recommended Defendants' hernia mesh products to friends or family members, Plaintiffs should be allowed to conduct further discovery to determine, among other things, when and to whom the recommendations were made, whether the recommendations were followed, whether the individuals had a similar medical profile to Mr. Milanesi, and whether the individuals experienced any complications. However, the details of whether the recommendations were actually followed, whether any complications occurred, or other details of any such recommendations are not relevant—as the Court has stated, any such recommendation may only be considered in terms of Defendants' knowledge and intent. Whether any complications occurred as a result of the recommended use of Defendants' product is irrelevant as to what Defendants' employees knew when they recommended the product. Therefore, evidence and testimony of decision makers' personal experience and recommendation of Defendants' polypropylene and/or ePTFE hernia mesh products will be permitted for the sole purpose of showing Defendants' knowledge and state of mind, and no additional discovery will be permitted. Further, the Defendants have represented that they will offer only three high-level executives for such testimony. Prior to such testimony, the record must clearly establish that the witness had a high-level decision making authority within the defendant corporation.

IV. Conclusion

For the reasons set forth above, the Court **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' MIL No. 4 (ECF No. 202). The Court will allow limited testimony regarding decision makers' personal use and/or recommendations of Defendants' polypropylene and/or ePTFE hernia mesh, but the Court will give a limiting instruction to the jury that the evidence may only be considered only as it relates to notice and may not be considered as evidence that the Defendants'

products are safe and effective. Plaintiffs will not be permitted extra discovery regarding the personal use or recommendations.

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

11/30/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE